REMARKS

Status of the Claims

Claims 47-60 are pending in the application. Claims 47, 48, 49, 50, 53, and 54 have been amended. Claim 47 has been amended to delete the terms "pharmaceutically active metabolite of said compound" and "or metabolite." Claims 47 and 50 have been further amended to recite "$=N(R^3)(R^4)$." As with claim 47, claims 48, 49, and 50 have also been amended to delete the term "metabolite" (or reference to metabolites). Claim 53 has been amended to recite "[t]he pharmaceutical composition according to claim 50, wherein said composition is included in a delivery platform selected from the group consisting of ~~administered as~~ a sterile solution, a suspension, and an ~~or~~ emulsion, and wherein the pharmaceutical composition is present in the delivery platform in a single or divided dose." Support for this amendment can be found in claim 53 as originally filed. Claim 54 has been amended to recite "[t]he pharmaceutical composition according to claim 50, wherein said composition is included in a delivery platform selected from the group consisting of~~administered as~~ a capsule and a ~~or~~ tablet, wherein the capsule or tablet comprises ~~containing~~ a single or divided dose of said compound." Support for this amendment can be found in claim 54 as originally filed.

Objections to the Claims

Claims 53 and 54 were objected to under 37 CFR 1.75(c), as allegedly being of improper form for "failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Both claims 53 and 54 refer to a method step, which is not present or supported in claim 50 which, is drawn to a composition." (Office Action page 5). In response to this objection, Applicants have amended claims 53 and 54 to recite a pharmaceutical composition having proper dependence on claim 50.

Rejections Under 35 U.S.C. § 112

Claims 47-57 were rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly "does not contain enabling disclosure for 'metabolite.'" (Office Action,

page 3). Applicants have deleted reference to the term "metabolite" in these claims. Accordingly, Applicants respectfully submit that this rejection is obviated in view of the amended claims.

Claim 55 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enabling disclosure. According to the Examiner, "[t]he specification at page 31 line 18 discloses that the composition may be molded into a solid implant. It is not clear from the specification whether the implant is a solid material inserted into the biodegradable polymer or an implant for insertion into the body." (Office Action, page 5). In response to this rejection, Applicants submit that the term "solid implant" would be understood by a person having skill in the art as being contemplated for insertion into the body. Accordingly, Applicants submit that this claim term is fully enabled by Applicants specification in view of the knowledge of a person skilled in the art.

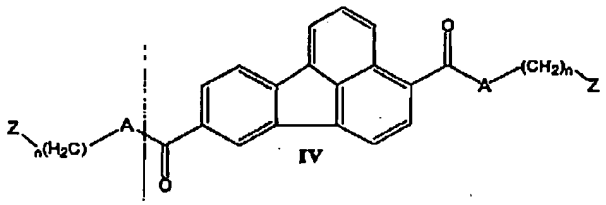
Claim 47, along with claims 48-57, were rejected under 35 U.S.C. § 112, second paragraph. According to the Examiner, "[t]he term $N(R^3)(R^4)$ is not clear because it lacks a point of attachment." Applicants have amended this claim to recite "$-N(R^3)(R^4)$," thereby indicating that the point of attachment to the moiety is to the nitrogen atom.

Rejections Under 35 U.S.C. § 103(a)

Claims 47-57 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent Nos. 4,041,165 and 3,937,833 to Shemano ("Shemano '165" and "Shemano '833" respectively). (Office Action, page 6). According to the Examiner, both Shemano references "teach related fluoranthene derivatives." (*Id.*). While the Examiner admits that "[p]atentees differ in that the compounds contain piperidine instead of piridyl attached to the bi substituted linking groups," the Examiner nevertheless maintains that "[it] would have been obvious to one of ordinary skill in the art to use one heteroaryl, e.g. piridyl, in lieu of another, as the results would not have been unexpected." (*Id.* at 6-7). The Examiner also states that the "references read on heteroaryl substituents per se." (*Id.* at 6). For the reasons explained below, Applicants respectfully traverse this rejection.

Applicants' claim 47, in relevant part, recites:

> A compound of the Formula IV:



IV

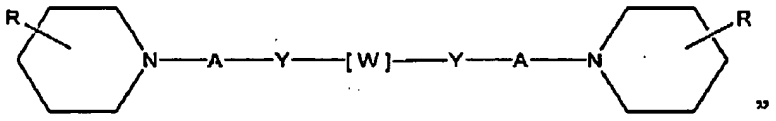
wherein:

n is 0 to 4;

A is CH_2, O, or S; and

Z is a substituted or unsubstituted aryl or heteroaryl, or = $N(R^3)(R^4)$, wherein R^3 is a substituted or unsubstituted aryl or heteroaryl, and R^4 is hydrogen, a substituted or unsubstituted lower alkyl, lower alkenyl, heterocycloalkyl, alkoxy, aryloxy, alkylamino, arylamino, or R^3 and R^4 are taken to form a substituted or unsubstituted five to six membered aromatic ring;

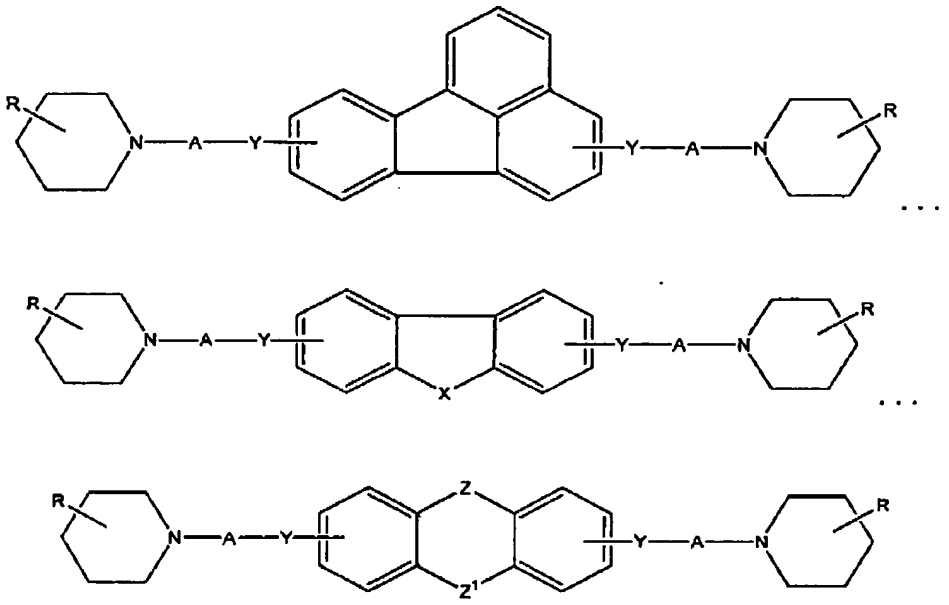
In contrast to this claim, Shemano fails to teach or suggest compounds having aromatic or aromatic heterocyclic groups corresponding to substituent Z. Instead, Shemano teaches that his disclosed compounds are ***bis-piperidino***alkylene derivatives (i.e., compounds having two piperidine groups). For example, Shemano generally discloses that "[b]is-basic substituted aromatic polycyclic compounds of the following structure are useful in treating conditions of delayed hypersensitivity:



"

(Shemano '833, col. 2, ll. 4-10). Shemano goes on to disclose that, while the group [W] can vary, a common characteristic of ***all*** of his disclosed compounds is the presence of two piperidine groups. In this regard, Shemano states:

> The compounds of this invention are ***bis-piperidino***alkylene derivatives . . . as represented by the following respective Formulas



(*Id.*, col. 2, l. 32 to col. 3, l. 5). Indeed, in introducing his invention, Shemano states that "[t]his invention relates to the use of bis-basic substituted aromatic polycyclic derivatives ***wherein the basic substituents contain a piperidino radical*** for treating conditions of delayed hypersensitivity." (*Id.*, col. 1, ll. 5-12 (emphasis added)). Accordingly, the presence of two piperidine groups is a common, if not critical, feature of all of Shemano's disclosed compounds.

Moreover, nowhere does Shemano teach or suggest substituting the two piperidine groups of his disclosed compounds for other substituents. Applicants note, in this regard, that "[t]o establish a *prima facie* case of obviousness in a . . . chemical composition situation, as in any other 35 U.S.C. 103 case, it is essential that Office personnel find some motivation or suggestion to make the claimed invention in light of the prior art teachings. See, e.g., *In re Brouwer*, 77 F.3d 422, 425 37 USPQ2d 1663, 1666 (Fed. Cir. 1996) ("[T]he mere possibility that one of the esters or the active methylene group-containing compounds . . . could be modified or replaced such that its use would lead to the specific sulfoalkylated resin recited in claim 8 does not make the process recited in claim 8 obvious 'unless the prior art suggested the desirability of [such a] modification' or replacement.") (MPEP § 2144.08).

Here, Applicants respectfully submit that no suggestion or motivation exists to modify the teachings of Shemano in the manner proposed by the Examiner, especially when Shemano teaches that two piperdine groups are a common, if not defining, characteristic of all of his disclosed compounds. Shemano's piperdine compounds, i.e., compounds without aromaticity, do not read on or have the reactive or inherent characteristics of the claimed heteroaryl substituents, compounds with aromaticity. Accordingly, Applicants request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

In view of the foregoing, withdrawal of the rejections and allowance of the current pending claims is respectfully requested. If the Examiner believes that the pending claims could be allowed with minor changes, the Examiner is invited to telephone the undersigned to discuss an Examiner's Amendment.

Applicants hereby authorized the Commissioner to please charge our Deposit Account No. 22-0185, in the amount of $60.00 for a one-month extension of time, under Order No. 22227-00003-US-2 from which the undersigned is authorized to draw.

Dated: 6/9/05

Respectfully submitted,

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